Exhibit C

Report for Gynecare TVT-Secur

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I. Background

a. Education and Training

I am a full-time practicing urologist in Lee County, Florida. I graduated with honors from the University of Pennsylvania in Philadelphia, Pennsylvania in 1986 with a Bachelor of Arts in Biology. My Doctor of Medicine degree was earned from Washington University, Saint Louis, Missouri in 1990. Subsequently, I completed a six year residency in Urology at the University of Rochester, Rochester, New York. My final year of urology training included serving as the Chief Resident in Urology.

Board certification was completed in 1999 after a single attempt. Board recertification was completed in 2007. Board certification in urology requires completing a certified urology residency program, the recommendation of the head of that urology program, and passage of oral and written exams. Subsequently, maintaining standards of certification is required. I am a Diplomate of the National Board of Medical Examiners, and a current member of the American Urological Association, the Southeastern Section of the American Urological Association, and the Lee County Medical Society. I have surgery privileges in the Lee Memorial Health System and Gladiolus Surgery Center in Fort Myers, Florida. I previously served on the Credentialing Committee and Medical Executive

Committee of the above health system. My curriculum vitae is attached to this report.

b. Clinical Experience with SUI Treatments

Prior to, during, and after my residency training, I was trained on many different techniques for treating stress urinary incontinence. These include retropubic colposuspension, laparoscopic urethropexy, needle suspensions, pubovaginal slings, mid-urethral slings, bulking agent injections, and artificial urinary sphincter. Soon after completing my residency, I was trained and began performing mid-urethral slings that utilized synthetic mesh. Prior to this, I was performing pubovaginal slings utilizing allograft, xenograft, and cadaveric tissue.

After completing my residency, I mostly performed non-mesh sling procedures and retropubic colposuspensions (Burch procedures). However, I have utilized all methods listed above since I began treating SUI.

Over the last decade, the vast majority of continence procedures performed in the United States have included the mid-urethral sling using synthetic mesh. These include the retropubic TVT, transobturator TVT-O, transobturator slings using the out-to-in method, the TVT-Abbrevo, and mini-slings including the TVT-Secur. I have performed over 600 of these procedures, several hundred of which were TVT-Secur procedures.

I have served as a preceptor for American Medical Systems, training other surgeons on the use of the Monarc Subfascial Hammock mid-urethral sling. I have also served as a Preceptor and Consultant for Ethicon/Gynecare for the TVT-O and TVT-

Secur devices, training both urologists and gynecologists on the use of both devices.

Compensation for my work in this case is $500 per hour. I have never previously provided expert testimony. A copy of my curriculum vitae is attached to this report, along with a list of materials I have reviewed in connection with forming the opinions included in this report, some of which may be used as exhibits at trial. The opinions set forth in this report are based on my education, training, and experience, as well as the literature and materials cited in this report and included on the attached list of materials reviewed. I hold all of the opinions set forth in this report to a reasonable degree of scientific and medical certainty. If I receive additional materials prior to the time of trial, I reserve the right to supplement this report.

II. Urinary Incontinence

a. Types, Definitions, Risk Factors, and Diagnosis

Urinary incontinence is defined as involuntary urine loss. Particular types of incontinence include stress incontinence (urine leakage due to coughing, laughing, sneezing, exercise, etc.), urge incontinence (urine leakage accompanied by urgency), and overflow incontinence (urine leakage resulting from bladder failure.) Mixed incontinence is typically a combination of SUI and urgency incontinence. Diagnosis of the above conditions is made from a combination of patient history, physical examination, and ruling out other treatable medical conditions that cause involuntary urine loss. Additional assessments can be utilized to make and clarify this condition, such as a voiding diary, urodynamic evaluation, and pad weight testing.

Urinary incontinence has been documented to affect up to 50% of women in their lifetime. SUI affects approximately 15% of women, which equates to tens of millions of American women. The cost of addressing this problem has escalated to over $1 billion per year.

Risks factors for incontinence are typically multifactorial. Obesity, smoking, vaginal deliveries, prior pelvic surgery or radiation, chronic coughing, and hereditary factors commonly contribute to involuntary urine loss. Certain medications can contribute or cause all types of incontinence. Additional but less common factors include neurologic conditions such as stroke, multiple sclerosis, Parkinson's disease, spinal cord injury, and excessive fluid intake.

b. Impact on Quality of Life

All forms of incontinence can have devastating impact on women's quality of life. Daily activity adjustments range from changing undergarments throughout the day to making extra trips to purchase incontinence pads to discontinuing exercise and avoiding social events to becoming homebound. I have had the opportunity to see patients who experience all of the above, as well as the effects this has on spouses and family. The degree of embarrassment can be dramatic enough to make women quit their job, avoid contact with others, and become social recluses. The financial, emotional, sexual, and physical problems that can arise in these women can be horrible.

III. Treatment Options for SUI

The severity of SUI and its accompanying degree of bother occupy a spectrum. This condition requires intervention when a patient finds the degree of involuntary urine loss to be

problematic or bothersome. Treatments include both non-invasive and invasive options. Frequently, multiple modalities are employed depending on the patient's needs and goals.

a. Non-Surgical SUI Treatment Options

There are a multitude of non-invasive, non-surgical treatment options for SUI. Some options simply provide a solution to saturating oneself with urine. These include absorbent pads, adult diapers, and a chronic catheter that drains the bladder into a retrieval bag. Disposable undergarments are commonly utilized and collectively cost patients billions of dollars per year. Non-surgical treatments that attempt to improve or cure SUI are quite varied in approach and mechanism of action. These include behavioral modification, pelvic muscle floor exercises, biofeedback therapy, electrical stimulation therapy, vaginal weights, and occlusive devices such as pessaries, tampons, or intravaginal bladder neck elevation implants. A motivated patient will typically demonstrate improvement with the above treatments, but rarely cure or provide longstanding sustained improvement. There are no FDA approved medications for the treatment of SUI. Several medications have been used in an off-label setting. However, no studies have shown any significant degree of effectiveness.

b. Surgical SUI Treatment Options

Treatment for SUI has evolved over the last several decades. Retropubic colposuspension, anterior colporrhaphy, and retropubic urethropexy used to be performed commonly, but not currently. Due to decreased invasiveness and improved efficacy, most continence surgeons have migrated to various

types of vaginal sling surgery over the last 10 years.[1] Sling types include mesh and non-mesh procedures; pubovaginal and mid-urethral variations; retropubic, obturator, and mini-sling categories. Transurethral or periurethral bulking material injection and artificial urinary sphincter are treatment options for use in specific clinical situations. Bulking material injection is less effective and may need to be repeated multiple times. The artificial urinary sphincter requires a very invasive, complex procedure typically performed at specialty centers. The lower effectiveness of these procedures makes them poor initial treatment options.

All continence surgeries have similar risks including: bleeding, infection, persistent or recurrent SUI, voiding dysfunction including overactive bladder symptoms and urinary retention, chronic pain, dyspareunia, injury to the vagina/urethra/bladder/ureters/pelvic blood vessels/pelvic nerves/bowel/pubic bone, and wound healing complications. Synthetic mesh erosion is unique to mesh-inclusive procedures, although non-absorbable sutures used in non-sling procedures can also erode through surrounding tissues. All of the above procedures include the potential need for reoperation to address certain complications.

Retropubic urethropexy, also known as needle suspension, was a previously common procedure which is now rarely, if at all, performed. This surgical technique involved small lower abdominal incisions through which a stiff metal guide was passed through the pubocervical fascia, just lateral to the

[1] Chughtai BI, et al., Midurethral Sling Is the Dominant Procedure for Female Stress Urinary Incontinence: Analysis of Case Logs From Certifying American Urologists. Urology 2013 Dec;82(6):1267-71; Clemons JL, et al., Impact of the 2011 FDA Transvaginal Mesh Safety Update on AUGS Members' Use of Synthetic Mesh and Biologic Grafts in Pelvic Reconstructive Surgery. Female Pelvic Med Reconstr Surg 2013;19:191-98; IUGA Stress Urinary Incontinence – A Guide for Women (2011).

proximal urethra on both the right and left side. This was followed by anchoring nonabsorbable suture to the pubocervical fascia with or without inclusion of the vaginal wall. The other end of the suture was passed back through the abdominal incision, followed by lifting of the anterior vagina which included both the proximal urethra and bladder neck after the abdominal suture was tied. This outpatient procedure commonly resulted in extended postoperative pain due to pressure placed on the lower abdominal fascia and muscle. As more surgeons became trained in more effective and durable vaginal sling procedures, the retropubic urethropexy was abandoned.

Retropubic colposuspension—more specifically, the Burch procedure—is an effective surgical treatment for SUI. This procedure requires a sizeable abdominal incision and entry into the abdominal cavity. The anterior vaginal wall is elevated with suture placed through pubocervical fascia, then anchored to Cooper's ligament, a structure adherent to the bony pelvis. This procedure adds little additional morbidity and recovery when performed concurrently with necessary extirpative surgery of the uterus, ovaries, fallopian tubes, and cervix. However, as a sole procedure, the retropubic colposuspension carries a longer operative time, a longer hospital stay, increased postoperative pain, longer convalescence, and typical return to work and strenuous activity in 4-6 weeks. The Burch procedure can also be performed laparoscopically, resulting in a shorter hospital stay and more prompt return to normal daily activity. This procedure is technically more difficult and highly variable regarding how it is performed. Studies have demonstrated that the success rates in providing continence are at best, similar to—with some studies demonstrating inferior results when compared to—newer and less invasive techniques such as mid-urethral slings. Some

long-term studies have shown success rates with the Burch procedure to drop significantly after ten years. For example, the Kjolhede 14-year study showed a decline in cure rates with only 19% of patients reporting that they were completely continent.[2] The Alcalay long-term study of the Burch colposuspension showed declining cure rates for 10-12 years, at which point a plateau of 69% was reached.[3]

The risks of retropubic or laparoscopic colposuspension are listed above. Additional risks of all surgeries that require entrance into the abdominal cavity or retropubic space include injury to any intra-abdominal or retropubic structures, ileus, incisional hernia, and future bowel obstruction due to adhesions. As compared to sling procedures, Burch procedures have higher rates of wound infection, bowel injury, and vaginal and bladder perforation. For patients considering the Burch procedure versus pubovaginal sling—described below—the latter is recommended to maximize cure of SUI.[4]

Bladder neck fascial slings, also known as pubovaginal slings, have been performed for decades. These procedures became more popular in the early 1990s as surgeons wanted less invasive and more effective alternatives. The patient undergoing a pubovaginal sling typically had an outpatient procedure or an overnight hospital stay. However, the vaginal aspect of the surgical dissection was extensive and accompanying blood loss could be significant. The patient also typically required a small abdominal incision and suprapubic catheter which added to morbidity. The surgical technique to

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[2] Kjolhede P, Long-term efficacy of Burch colposuspension: a 14-year follow-up study. Acta Obstet Gynecol Scand 2005;84:767-72.
[3] Alcalay M, et al., Burch colposuspension: a 10-20 year follow-up. Br J Obstet & Gynaecol, 1995 Sep;102(9):740-45.
[4] Schimpf MO, et al., Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 2014;211:71.e1–27.

perform these procedures is highly varied with no simple, easily reproducible technique available. In addition, the various sling materials included: synthetics, autologous, allograft, xenograft, and in-situ tissue. The quality and biocompatibility of these different slings made reproducibility difficult. Safety, durability, and outcomes data were lacking. Early-used synthetic materials like Gore-Tex and Dacron turned out to have an excessive complication rate including fistulalization and erosion. Allograft, cadaveric, and xenograft materials were highly inconsistent in quality, with the last two choices also introducing the possibility of infection and patient refusal based on religious or personal reasons. They also present the possibility—albeit remote—of disease transmission despite sterilization efforts.

These earlier sling types have the same potential complications of mid-urethral slings, with the addition of a more prolonged recovery along with requiring several weeks before returning to work. Post-operative voiding dysfunction, including urinary retention, irritative and/or obstructive voiding symptoms was common.

On occasion, I still utilize the pubovaginal sling in certain circumstances. These include cases of severe intrinsic sphincter deficiency with a failed prior procedure; stress incontinence with a rigid and fixed urethra; and failed prior procedures that resulted in bladder or urethral injury. I always provide the patient with multiple options for stress urinary incontinence surgery, including mid-urethral sling with mesh, pubovaginal sling with non-mesh alternatives, and bulking material injection. After discussion of all risks and benefits, patients almost always prefer the less-invasive, more effective option that provides the quickest return to work and full range of activities: the mid-urethral mesh sling.

IV. Ethicon's TVT and TVT-O Mid-Urethral Slings

a. Historical Use of Polypropylene

Polypropylene mesh has been utilized by surgeons for more than 50 years. Polypropylene suture continues to be one of the most commonly used types of non-absorbable suturing material today. The most popular use has always been for hernia repair surgery. Hernia recurrence has decreased dramatically since incorporation of polypropylene mesh. The mesh has been used for decades as an integral part of various urologic and gynecologic procedures. Many biotech companies continue to provide polypropylene mesh in various sizes and surgical procedure kits to assist surgeons in providing their patients the best outcomes possible.

b. Development of Tension-Free Vaginal Tape (TVT) Using Prolene Mesh

In the mid-1990s Dr. Ulf Ulmsten, a Swedish surgeon, developed an innovative surgical technique for the treatment of female stress urinary incontinence after many years of research. The technique involved placing a sling at the midurethra rather than at the bladder neck. The technique was performed vaginally, involved very small incisions, and could be performed under local anesthesia in about thirty minutes as an outpatient procedure. The procedure was based on what Dr. Ulmsten and Dr. Petros called the "Integral Theory," which posited that both stress and urge incontinence symptoms may derive from laxity in the vagina "caused by defects within the vaginal wall itself, or its supporting structure i.e. ligaments, muscles, and their connective tissue

insertions."[5] The procedure was designed to compensate for that laxity by correcting the "inadequate urethral support from the pubourethral-vesical ligaments and the suburethral vaginal wall. Ulmsten and colleagues experimented with a variety of sling materials, including Gore-Tex and Mersilene, but found that those materials had an approximately 8–10% rejection rate. The surgeons ended up selecting lightweight, large-pore, monofilament, knitted Prolene mesh as the most suitable mesh material to use for the sling after finding that there were no rejections or healing defects with the Prolene slings. The surgeons found that "[t]he small incisions and canals involved with this technique minimized the surgical trauma and enabled the operation to be performed under local anesthesia."[6] One of Ethicon's medical directors met with Dr. Ulmsten in 1995 to learn more about the procedure, and Ethicon ultimately purchased the rights to the sling device, which became known as the TVT device.

Ethicon's TVT device consists of a strip of lightweight, Type I,[7] monofilament, knitted Prolene mesh 1.1 cm wide and 45 cm long attached to two reusable stainless steel trocars used for implanting the mesh. The mesh is covered with sheaths that are removed once the mesh is placed. Implantation of the TVT device involves making a small incision under the midurethra and two small suprapubic incisions on the abdomen. The trocars with the mesh attached are passed through the

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[5] Petros P and Ulmsten U, An Integral Theory of Female Urinary Incontinence – Experimental and clinical considerations. Acta Obstet Gynecol Scand 1990;69 Suppl 153:7-31.

[6] Ulmsten U, et al., An ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence. Int Urogynecol J 1996;7:81–86.

[7] "Type I" meshes are totally macroporous meshes containing pores larger than 75 microns, "which is the required pore size for admission of macrophages, fibroblasts (fibroplasia), blood vessels (angiogenesis) and collagen fibers into the pores…." Amid PK, Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia 1997;1:15–21.

suburethral incision, passing the mesh through the retropubic space and exiting through the suprapubic abdominal incisions. Once the mesh is properly placed—in a tension-free manner—the trocars and sheathes are removed, the suburethral incision is closed, along with the suprapubic incisions.

The TVT device became very popular, very quickly for several key reasons. This new procedure provided a less invasive option than all other currently employed alternatives. Easy reproducibility of the procedure and a quick physician learning curve made the TVT attractive to most surgeons who performed continence surgery. The low cost self-contained kit required minimal additional instrumentation, and minimal surgeon assistance allowed the procedure to be promptly adopted at all varieties of surgical facilities. Various types of anesthesia were utilized depending on the requirements and desires of the patient, surgeon, and anesthesiologist. This typically outpatient procedure requiring less than 30 minutes of operating room time benefited patients. Patients usually were discharged without indwelling catheters, and wound closure techniques required no specific post-operative office visit. Also, procedure efficacy was immediately available to patient and surgeon.

Studies demonstrating the effectiveness of TVT procedures have been published in urology and gynecology journals throughout the world. There are currently more than 100 randomly controlled trials that have been produced at a multitude of academic medical centers, making this product the most commonly studied continence procedure in history. Many published reviews have indicated the overall effectiveness and acceptable side-effect profile of this mesh

product.[8] The quality of these studies have been aggressively dissected and critiqued by academic physicians worldwide revealing the identification of high quality study design and investigation. Currently, TVT procedures have widespread acceptance and has been identified by most continence surgeons as the current "gold standard."

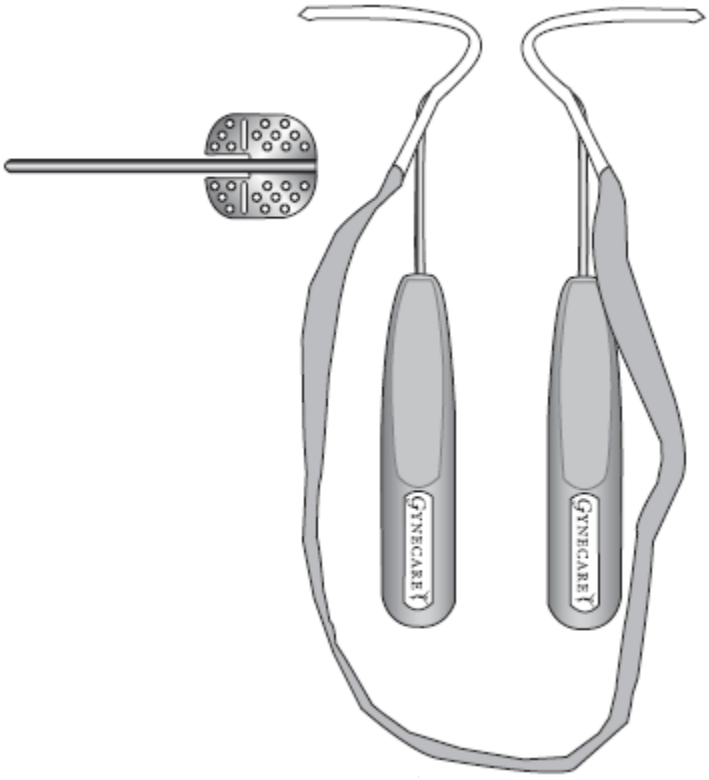
As a urologic surgeon, I have been performing sling procedures my entire professional career. Initially I performed pubovaginal slings using cadaveric, allograft, and xenograft as supportive material. Although an effective procedure, I found the variability of biologic sling material was dramatic and many times unsatisfactory. In addition, the depth of vaginal

[8] Nilsson CJ, Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J, 2013 Aug;24(8):1265–9; Olsson I, et al., Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence. Int Urogynecol J 2010;21:679-683; Serati M, et al., Tension-free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 10-Year Follow-Up. Eur Urol 2012;61:939-946; Heinonen P, et al., Tension-free vaginal tape procedure without preoperative urodynamic examination: long-term outcome. Int J Urol 2012 Nov;19(11):1003-9; Laurikainen E, et al., Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. Eur Urol. 2014 Jun;65(6):1109-14; Aigmueller T, et al., Ten-year follow-up after the tension-free vaginal tape procedure. Am J Obstet Gynecol 2011 Nov;205(5):496.e1-5; Svenningsen R, et al., Long-term follow-up of the retropubic tension-free vaginal tape procedure. Int Urogynecol J 2013 Aug;24(8):1271-8; Wu J, Surgical therapies of female stress urinary incontinence: experience in 228 cases. Int Urogynecol J 2010;21:645-649; Hil Song P, The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence. 2009 BJU Int, 104, 1113-1117; Christian J, et al., Long-term outcomes of TVT and IVS operations for treatment of female stress urinary incontinence: monofilament vs. multifilament polypropylene tape. Int Urogynecol J 2009;20:703-709; Kuuva N, et al., Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women. Acta Obstetrica et Gynecologica 2006;85:482-487; Bjelic-Radisic V, Patient related outcomes and Urinary Continence Five Years after the Tension-Free Vaginal Tape Operation. Neurourology and Urodynamics 2011;30:1512-1517; Liapis A, Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5 and 7 year follow-up. Int Urogynecol J 2008;19:1509-1512; Jelovsek JE, et al, Randomized trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up. BJOG 2008;115:219-225; McCracken GR, Five Year Follow-up Comparing Tension-Free Vaginal Tape and Colposuspension. Ulster Med J 2007;76 (3) 146-149; Chene G, Long-term results of tension-free vaginal tape (TVT) for the treatment of female urinary stress incontinence. European Journal of Obstetrics and Gynecology and Reproductive Biology, 2007;134:87-94.

and pelvic dissection along with problematic bleeding kept me searching for a better alternative. After the initial studies reporting the efficacy and safety of polypropylene slings became available, I began performing the retropubic TVT, soon followed by the outside-in transobturator approach, then the inside-out transobturator approach utilized with the Ethicon TVT-O device. Following the incorporation of transobturator slings into my practice, I started also using mini-slings.

Following the success of the TVT device, surgeons developed a method of implanting the TVT mesh via a transobturator approach in order to reduce the incidence of bladder injury, retention, and other complications. Delorme and colleagues developed a procedure that involved passing the mesh tape through the obturator foramina from an outside-to-inside approach.[9] The TVT-O device was developed by Dr. Jean de Leval in 2003 in an attempt to reduce the amount of urethral and bladder injuries that could result from an outside-to-inside passage. The TVT-O utilizes the same lightweight, large-pore, knitted monofilament Prolene mesh as the TVT device. The mesh in the TVT-O device is 1.1 cm wide by 45 cm long. The mesh is covered by plastic sheathes, and is attached to single-use helical passers. The device also includes an Atraumatic Winged Guide that facilitates the passage of the helical passers through the dissection tract. Rather than passing through the retropubic space and exiting through suprapubic incisions, the mesh is passed laterally through the obturator foramina, exiting through small incisions in the patients' medial thighs. By avoiding the retropubic space, the device's transobturator passage avoids potential injury to the bladder and bowel.

[9] De Leval J, Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence: Transobturator Vaginal Tape Inside-Out. Eur Urol 2003;44:724-30; Delorme, E, Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol 2001;11(6):1306.



While continuing to use synthetic polypropylene mesh as my sling material of choice, I gravitated to the TVT-O for several reasons. I found the transobturator procedure technically easier and more reproducible to perform. The complication of bladder, urethral, major vascular structures, and bowel perforation became almost nonexistent due to a more localized technique. I was and still am a proponent of a more horizontal "hammock" sling position than the more vertical "U-type" sling position. In both my early and current experience, the "hammock" position of the TVT-O resulted in less post-operative irritative and obstructive voiding symptoms. This has also been supported by multiple high-quality randomized controlled studies. From an aesthetic viewpoint, many patients also prefer bilateral inner thigh incisions rather than lower abdominal incisions. The TVT-O is one of my most commonly used devices to treat SUI.

There is a significant body of data supporting the use of synthetic mesh mid-urethral slings in general—and the TVT-O device in particular—for the treatment of female SUI.[10] Because the mesh used in the TVT-O device is the same lightweight, Type I Prolene mesh used in the TVT-Secur, these studies also support the safety of the mesh used in the TVT-Secur device.

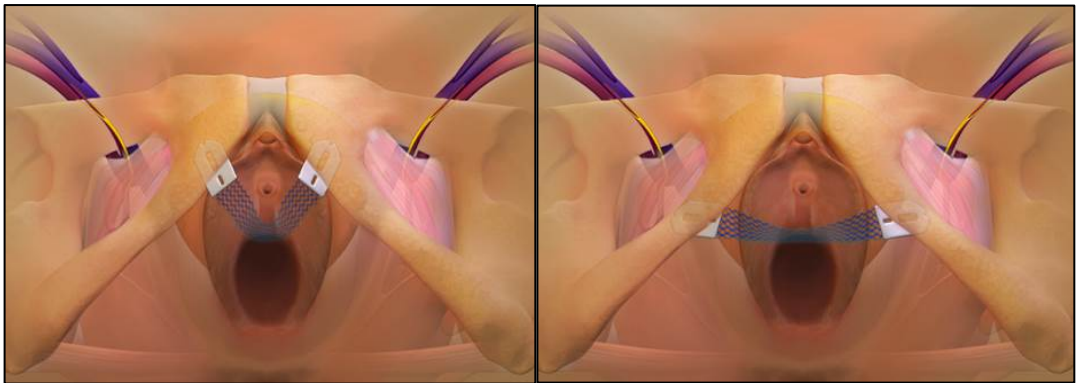
In 2006, Ethicon released the TVT-Secur sling. It was a novel device that was considered a "mini-sling" and could be

[10] De Leval J, Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence: Transobturator Vaginal Tape Inside-Out. Eur Urol 2003;44:724-30;Waltregny D, et al., Inside Out Transobturator Vaginal Tape for the Treatment of Female Stress Urinary Incontinence: Interim Results of a Prospective Study After a 1-Year Minimum Follow up. J Urol 2006 Jun;175:2191–5; Waltregny D, et al., TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up. Eur Urol 2008;53:401–10; Cheng D and Liu C, Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. Eur J Obstet & Gynecol and Reprod Biol 2012;161:228–31; Liapis A, et al., Efficacy of inside-out transobturator vaginal tape (TVTO) at 4 years follow up. Eur J Obstet & Gynecol and Reprod Biol 2010;148:199–201; Angioli R, et al., Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective, Randomised Trial. Eur Urol 2010;58:671–77; Groutz A, et al., Long-Term Outcome of Transobturator Tension-Free Vaginal Tape: Efficacy and Risk Factors for Surgical Failure. J Women's Health 2011;20(1):1525–28; Serati M, TVT-O for the Treatment of Pure Urodynamic Stress Incontinence: Efficacy, Adverse Effects, and Prognostic Factors at 5-Year Follow-up. Eur Urol 2013;63:872–78; Laurikainen E, et al., Five-year Results of a Randomized Trial Comparing Retropubic and Transobturator Midurethral Slings for Stress Incontinence. Eur Urol 2014 Jun;65(6):1109–14; Athanasiou S, et al., Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: Why do tapes fail? Int Urogynecol J 2014;25:219–25; Novara G, et al., Complication Rates of Tension-Free Midurethral Slings in the Treatment of Female Stress Urinary Incontinence: A Systematic Review and Meta-Analysis of Randomized Controlled Trials Comparing Tension-Free Midurethral Tapes to Other Surgical Procedures and Different Devices. Eur Urol 2008;53:288–309; Ogah J, et al., Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence in Women: A Short Version Cochrane Review. Neurourol and Urodyn 2011 Mar;30(3):284–91; Ford AA, et al., Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database of Systematic Reviews 2015, Issue 7. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub3; Schimpf MO, et al., Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 2014 Jul;211(1):71.e1–71.e27; Tommaselli GA, et al., Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. Int Urogynecol J 2015 Sep;26(9):1253–68; Cox A, et al., Surgical management of female SUI: is there a gold standard? Nat Rev Urol 2013;10:78–89.

implanted via a single small vaginal incision. The device consisted of a 1.1 cm x 8.0 cm piece of Prolene polypropylene mesh with pieces of fleece made of Vicryl and PDS sandwiched on the ends. It was the same Type I, knitted, monofilament, lightweight mesh used in the TVT and TVT-O devices, and it was laser-cut. The Prolene polypropylene mesh was non-absorbable, but the fleece ends were absorbable. The device is pictured below.

Rather than being inserted through the use of trocars like the TVT and TVT-O devices, the TVT-Secur was implanted through the use of inserters. The TVT-Secur was developed in response to feedback from surgeons who sought surgical treatments that were even simpler and less-invasive in order to reduce the potential for complications. The device could be implanted in one of two approaches—a "hammock" approach like that used with the TVT-O device, or a "U" approach like that used with the TVT device—depending on surgeon preference.

Regardless of the approach chosen, the mesh was still placed at the midurethra, as with the TVT and TVT-O procedures.



"U" Approach **"Hammock" Approach**

I found the TVT-Secur to be less invasive than other surgical SUI treatments, to involve less tissue dissection, to cause less bleeding, and to result in no need for post-operative catheterization. The fact that the device could be implanted via a single incision meant that there were no non-vaginal wounds that had to heal or had the possibility of getting infected. The TVT-Secur was essentially pain-free for my patients, especially compared to other available treatments. I did not prescribe pain medication for my TVT-Secur patients unless they requested it, and they rarely did so. The patients were back to normal, non-strenuous activities within 2–3 days after the procedure. After a week, they were back to work. I would put them on restrictions for a month—no pool submersion, no sexual intercourse, and no strenuous exercise. The TVT-Secur was an excellent device to have in the surgeon's toolkit, especially for women in jobs such as teachers, waitresses, nurses, or other physically demanding jobs where they needed to get back as soon as possible to work. Overall, my TVT-Secur patients did great. If the TVT-Secur was still available, I would still be using it.

c. The safety and efficacy of the TVT-Secur mid-urethral sling.

The TVT-Secur was an extensively studied product. There were at least 83 TVT-Secur studies—nineteen of which were randomized controlled trials—from 2006 to November 2014. While the published literature reported varying efficacy rates for the TVT-Secur, a significant amount of literature, including several randomized controlled trials, reported very favorable efficacy.[11] Many studies reported success or satisfaction rates ranging from 76% (Shin 2011) to 94% (Neuman 2008). In the Tincello study published in 2011, the authors noted the TVT-Secur involved short operative times, reduced need for overnight hospital stays, and improved ability to have the procedure performed under only local anesthesia. They found

[11] Khandwala S, et al., Experience with TVT-SECUR sling for stress urinary incontinence: a 141-case analysis. Int Urogynecol J 2010 Jul;21(7):767-72; Tincello DG, et al., The TVT Worldwide Observational Registry for Long-Term Data: Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women. J Urol 2011; 186:2310–2315; Neuman M, Perioperative complications and early follow-up with 100 TVT-SECUR procedures. J Minim Invasive Gynecol 2008 Jul-Agu;15(4): 480-4; Meschia M, et al., TVT-secur: a minimally invasive procedure for the treatment of primary stress urinary incontinence. One year data from a multi-centre prospective trial. Int Urogynecol J Pelvic Floor Dysfunct 2009 Mar;20(3):313-7; Lee K-S, et al., A Prospective Multicenter Randomized Comparative Study Between the U- and H-type Methods of the TVT SECUR Procedure for the Treatment of Female Stress Urinary Incontinence: 1-Year Follow-Up. Eur Urol 2010;57:973–979; Oliveira R, et al., Short-term assessment of a tension-free vaginal tape for treating female stress urinary incontinence. BJU Int 2009 Jul;104(2):225-8; Tommaselli GA, et al., Efficacy and safety of TVT-O and TVT-Secur in the treatment of female stress urinary incontinence: 1-year follow-up. Int Urogynecol J 2010 Oct;21(10):1211-7; Tommaselli GA, et al., Tension-Free Vaginal Tape-O and –Secur for the Treatment of Stress Urinary Incontinence: A Thirty-Six-Month Follow-Up Single-Blind, Double-Arm Randomized Study. J Minimally Invasive Gynecol 2013;20(2):198–204; Shin YS, et al., Efficacy and safety of the TVT-SECUR and impact on quality of life in women with stress urinary incontinence: a 2-year follow-up. Korean J Urol 2011 May;52(5):335-9.

the efficacy of the sling—both objective and subjective—was comparable to that of the retropubic TVT sling.[12]

In 2011, Dr. Colin A. Walsh published a systematic review of TVT-Secur studies reporting 12-month outcomes. Ten studies involving a total of 1,178 women were included in the systematic review. While Walsh noted that the device's "long-term efficacy moving forward requires close scrutiny," he also noted that the TVT-Secur appeared "to be a safe procedure."[13] Walsh's review showed that among the 1,178 women studied, 76% were subjectively cured at 12 months. Only 1.5% of the women experienced a vaginal perforation, and only 2.4% of the patients experienced a mesh exposure. De novo OAB symptoms occurred in 10% of the patients, urinary retention in 2.3%, and UTI in 4.4%. Return to the operating room for complications occurred in only 0.8% of patients, and dyspareunia occurred in only 1% of the patients. Other studies have also reported low rates of dyspareunia with the TVT-Secur.[14]

Some studies have reported increased rates of exposure associated with the TVT-Secur, but most studies, as reflected in

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[12] Tincello DG, et al., The TVT Worldwide Observational Registry for Long-Term Data: Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women. J Urol 2011; 186:2310–2315.

[13] Walsh CA, TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months. BJUI 2011; 108: 652–657.

[14] Tommaselli GA, et al., Tension-Free Vaginal Tape-O and –Secur for the Treatment of Stress Urinary Incontinence: A Thirty-Six-Month Follow-Up Single-Blind, Double-Arm Randomized Study. J Minimally Invasive Gynecol 2013;20(2):198–204 (sexual function not adversely affected); Tang X, et al., Outcome and sexual function after transobturator tape procedure versus tension-free vaginal tape SECUR: a randomized controlled trial. Menopause 2014;21(6):1–5 (2.6% rate of dyspareunia); Tommaselli GA, Tension-free vaginal tape-obturator and tension-free vaginal tape-Secur for the treatment of stress urinary incontinence: a 5-year follow-up randomized study. Eur J Obstet & Gynecol and Reprod Biol 2015;185:151–55 (no reports of symptoms ascribable to vaginal erosion, such as malodorous discharge or dyspareunia).

the Walsh systematic review, reported a low incidence of exposure.[15]

A 2015 Cochrane review analyzed 81 separate studies involving 12,113 women. Fifty-five of the trials involving 8,652 women compared the use of the transobturator route and retropubic route. While the study did not include single-incision slings like the TVT-Secur, it does speak to the safety and efficacy of the mesh used in the TVT-Secur. The authors found that the overall rate of adverse events with retropubic and trans-obturator slings was low. In all of the studies comparing retropubic and trans-obturator slings, "there was significant improvement in sexual function from baseline scores during the follow-up period that spanned six to 24 months. . . . At 24-month follow-up, rates of superficial and deep dyspareunia were low, with no difference between the groups." The authors' analysis led them to conclude:

> "Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have a good safety profile. Irrespective of the routes

[15] Tommaselli GA, et al., Tension-Free Vaginal Tape-O and –Secur for the Treatment of Stress Urinary Incontinence: A Thirty-Six-Month Follow-Up Single-Blind, Double-Arm Randomized Study. J Minimally Invasive Gynecol 2013;20(2):198–204 (4.7% exposure rate); Lee K-S, et al., A Prospective Multicenter Randomized Comparative Study Between the U- and H-type Methods of the TVT SECUR Procedure for the Treatment of Female Stress Urinary Incontinence: 1-Year Follow-Up. Eur Urol 2010;57:973–979 (no mesh erosion); Tincello DG, et al., The TVT Worldwide Observational Registry for Long-Term Data: Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women. J Urol 2011; 186:2310–2315 (1.2% erosion rate); Hinoul P, et al., A Randomized, Controlled Trial Comparing an Innovative Single Incision Sling With an Established Transobturator Sling to Treat Female Stress Urinary Incontinence. J Urol 2011; 185(4):1356–1362 (7.3%); Hamer MA, et al., One-year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur. Int Urogynecol J 2013;24:223–229 (5% erosion rate); Barber MD, et al., Single-Incision Mini-Sling Compared With Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence; A Randomized Controlled Trial. Obstet & Gynecol 2012;119(2):328–337 (no mesh exposures).

> traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term. This review illustrates their positive impact on improving the quality of life of women with SUI."[16]

The Society of Gynecologic Surgeons Systematic Review Group published in 2014 a systematic review and meta-analysis of RCTs with at least 12 months of follow-up comparing a sling procedure to either another sling procedure or to the Burch procedure. The authors noted low complication rates with mini-slings such as the TVT-Secur. The data shows that TVT-Secur is safe, effective, and minimally invasive. When comparing mid-urethral slings (MUS) to the Burch procedure, they noted that the procedures have comparable rates of objective and subjective cure, and that MUS "may result in lower rates of perioperative adverse events such as blood loss, postoperative pain, operating room time, hospital stay, bowel injury, wound infection, and hematomas," whereas "Burch procedures may result in lower rates of erosion, overactive bladder symptoms, and groin pain." For women considering either a pubovaginal sling (either biologic or synthetic) or the TVT, the authors recommended the TVT for better subjective cure outcomes, and found that MUS "may result in lower rates of perioperative outcomes such as operating room time, blood loss, and hospital stay," whereas pubovaginal slings "may result in lower rates of adverse events such as urinary tract infection and vaginal perforation." The authors found that the summary estimate of incidence for dyspareunia with a mini-sling was only 0.74%. Overall, the authors concluded that "the evidence supporting use of MUS and pubovaginal slings is of

[16] Ford AA, et al., Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database of Systematic Reviews 2015, Issue 7. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub3.

high quality." When comparing mini-slings to TVT or TVT-O slings, the group found that the full-length slings had better cure rates, but the rates of post-operative bladder symptoms in trans-obturator and mini-slings was similar, and the rate of those symptoms was lower in mini-slings than retropubic slings. For exposure, the rate was similar for the TVT-Secur and TVT-O, but lower with the TVT. They also found dyspareunia was more common with mini-slings than full-length slings, but the absolute rates of dyspareunia were low for all types of slings.[17]

In 2015, Dr. Giovanni Tommaselli and colleagues published a systematic review and meta-analysis of medium- and long-term outcomes following implantation of synthetic mesh mid-urethral slings. They included data from 49 studies, and found that retropubic and trans-obturator slings had similar objective cure rates, but the latter had lower subjective cure rates. They found that randomized controlled trials comparing trans-obturator midurethral sling procedures to the TVT-Secur showed similar objective and subjective cure rates between the two. Persistent or chronic pain was reported in only 30 patients out of 2,432 trans-obturator patients (1.2%) and 13 out of 3,974 retropubic patients (0.3%). The authors found that both retropubic and trans-obturator procedures are backed by a high safety profile.

Based on the extensive body of data supporting the safety and efficacy of synthetic mesh midurethral slings, they have replaced the Burch retropubic colposuspension and pubovaginal slings as "the new gold standard first-line surgical treatment for women with uncomplicated SUI," whether

[17] Schimpf MO, et al., Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 2014;211:71.e1–27.

inserted via a retropubic or transobturator approach.[18] The mesh used in the TVT-Secur was the same mesh used in the gold standard TVT and TVT-O slings.

Numerous professional organizations have issued position statements or guidelines noting surgeons' widespread use and preference for midurethral slings. In 2014, the American Urogynecological Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) issued their Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence, which stated: "The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women." The position statement also notes that "[a] broad evidence base including high quality scientific papers in medical journals in the US and the world supports the use of the MUS as a treatment for SUI. There are greater than 2000 publications in the scientific literature describing the MUS in the treatment of SUI. These studies include the highest level of scientific evidence in the peer reviewed scientific literature." It also states: "This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence." The position statement also says "Full-length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current gold standard for stress incontinence surgery." TVT-Secur is not a full-length sling, but this

[18] Cox A, et al., Surgical management of female SUI: is there a gold standard? Nat. Rev. Urol. 2013;10:78–89.

nonetheless supports the safety of the mesh used in the TVT-Secur.[19]

AUGS & SUFU are not alone in their praise of midurethral slings. The American Urological Association's (AUA) Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence notes that "[s]uburethral synthetic polypropylene mesh sling placement is the most common surgery currently performed for SUI," and further states:

> "Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries. Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction. Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low. Furthermore, it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well. It is the AUA's opinion that any restriction of the use of synthetic polypropylene mesh suburethral slings would be a disservice to women who choose surgical correction of SUI."[20]

[19] AUGS-SUFU Position Statement on Mesh Midurethral Slings for SUI, 2014 Jan.
[20] AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence, 2011.

The 2012 American Urological Association's SUI Guidelines noted low complication rates for synthetic mid-urethral slings (1% incidence of pain, 0% incidence of sexual dysfunction).[21]

In September 2013, the National Institute for Health and Care Excellence issued its Clinical Guideline 171 titled "Urinary incontinence: The management of urinary incontinence in women." The guideline suggests that surgeons offer synthetic midurethral sling surgery, open colposuspension, or autologous rectus fascial sling if conservative management for SUI has failed. It goes on to note that surgeons should "use procedures and devices for which there is current high quality evidence of efficacy and safety" when deciding which synthetic midurethral slings to offer a patient. And it specifically lists the TVT and TVT-O slings as two of the devices for which there is currently high quality evidence of efficacy and safety.[22] Those two devices use the exact same mesh utilized in the TVT-Secur, and the mesh lays at the same place in the body—under the midurethra.

The International Continence Society published an ICS Fact Sheet in July 2013, which provides a background on urinary and fecal incontinence. That fact sheet notes that, "[w]orldwide, midurethral slings comprised of synthetic mesh have become the treatment of choice for SUI. Long-term data are robust and demonstrate durable efficacy with a very low complication rate, particularly in experienced hands."

In November 2015 the American College of Obstetricians and Gynecologists (ACOG) and AUGS issued their Practice Bulletin Number 155, providing clinical management guidelines for

[21] AUA Guidelines for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update (2012), Appendix A16.
[22] National Institute for Health and Care Excellence, Urinary incontinence: The management of urinary incontinence in women, Sept. 2013 at guidance.nice.org.uk/cg171.

obstetricians-gynecologists on urinary incontinence in women. The guidelines state that "[s]ynthetic midurethral slings demonstrate efficacy that is similar to traditional suburethral fascial slings, open colposuspension, and laparoscopic colposuspension," but are associated with fewer adverse events than suburethral fascial slings and less voiding dysfunction than open colposuspension. "For these reasons, midurethral synthetic mesh slings have become the primary surgical treatment for stress urinary incontinence in women." The guidelines also note that, while "controversy exists about the role of synthetic mesh used in the vaginal repair of pelvic organ prolapse, there are substantial safety and efficacy data that support the role of synthetic mesh midurethral slings as a primary surgical treatment option for stress urinary incontinence in women." The guidelines note that two meta-analyses observed significantly lower cure rates with single-incision slings than full-length slings, and suggests, as a result, that the surgeon should consider the risk-benefit profile for each procedure along with the patient's goals and expectations.

The TVT-Secur sling is only available in a laser-cut version. I have used mechanically cut TVT-O slings, and I have used laser-cut TVT-Abbrevo and TVT-Secur slings, and I have not found there to be a clinically significant difference in the way the mesh itself performs. In my patients in whom I implanted a TVT-Secur sling, I have not seen increased rates of pain, dyspareunia, erosions, exposures, recurrent incontinence, or re-operation as plaintiffs' experts have suggested, nor am I aware of published studies indicating the presence of such issues or any clinical significance. The strong efficacy and safety exhibited in the published literature on MUS predating the availability of laser-cut mesh slings is consistent with the strong efficacy and safety exhibited in the published literature since laser-cut mesh has been available. In my opinion, both

laser-cut and mechanically cut TVT mesh are safe and effective and state of the art.

Nor have I seen any clinically significant contraction in the TVT-Secur mesh slings that I have used. In my experience, tissue ingrowth occurs as expected following implantation of the sling, and while that scar tissue can be expected to contract to an extent, I have not seen contraction of the tissue that leads to problems.

Some have suggested that the mesh used in the TVT-Secur, TVT-O and other TVT devices is potentially carcinogenic. The published literature refutes any such idea.[23] Prolene polypropylene sutures have been used in millions of patients since the 1960s and I am unaware of any case reports of cancer associated with the use of those sutures. Prolene polypropylene mesh slings have been used in millions of SUI patients as well, and I am unaware of any case reports of cancer attributed to this type of mesh .

Plaintiffs' experts have offered the opinion that the mesh in the TVT family of products is cytotoxic and degrades. I disagree. Studies relied on by plaintiffs' experts such as the Clavé study or others that show SEM images of mesh fibers with surface cracking do not appear to account for pre-analysis alteration from explantation, handling, or processing. The Clavé study involved an analysis of a sample that was only 32 out of the original 100 specimens, and the authors did not explain how

[23] King A, et al, Current Controversies Regarding Oncologic Risk Associated with Polypropylene Midurethral Slings. Curr Urol Rep 2014;15:453; Moalli P, et al., Polypropylene mesh: evidence for lack of carcinogenicity. Int Urogynecol J 2014, DOI 10.1007/s00192-014-2343-8; AUGS & SUFU, Frequently Asked Questions by Providers—Mid-urethral Slings for Stress Urinary Incontinence. (available at http://www.augs.org/p/bl/et/blogaid=194); Linder BJ, Evaluation of the local carcinogenic potential of mesh used in the treatment of female stress urinary incontinence. Int Urogynecol J 2016 DOI 10.1007/s00192-016-2961=4.

that particular sample was selected. The surface cracking shown in the study could be from handling or explantation of the mesh, or it could be cracked biomaterial on the outside of the mesh.[24] If the mesh used in the TVT-Secur degraded as opined by plaintiffs' experts, surgeons would routinely see that in their practice and the slings would not have the good efficacy and safety results that they have. I have not observed any clinically significant degradation of TVT-Secur slings in my practice, nor have I heard any reports from colleagues regarding any such degradation. Nor have I seen any cytotoxicity in the mesh. Again, if the mesh was cytotoxic, it would not be well-tolerated by the body as reported in the numerous studies referenced above.

Plaintiffs' experts have also offered the opinion that larger pore or lighter weight meshes would have been safer to use in the TVT-Secur sling. I disagree. I am not aware of any studies showing that it would be feasible to use meshes like Ultrapro, Vypro, or Gynemesh PS as a transobturator sling material. Plaintiffs' experts have suggested an article by some Turkish surgeons looking at an incontinence procedure using Vypro, Ultrapro, and Prolene light mesh indicates those materials could have been used as an alternative design for the TVT-Secur. But the procedure performed by the surgeons in that study is very different from the TVT-Secur procedure and thus the study does not demonstrate the feasibility of using those meshes as a midurethral transobturator sling. Furthermore, there were complications such as vaginal erosions, urine retention, incontinence, and de novo urgency experienced in the Vypro, Ultrapro, and Prolene light groups.[25] Other studies

[24] Clavé A, et al., Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J 2010;21:261–270.
[25] Okulu E, et al., Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications. Scand J Urol 2013;47:217–24.

have shown poor tolerance of Vypro mesh when implanted in pelvic floor surgery.[26] In my opinion, the pore size and weight of the mesh used in the TVT-Secur is optimal, as evidenced by the extensive evidence of efficacy and safety discussed above.

Plaintiffs' expert witnesses have also contended that the TVT-Secur should not have been designed for placement in a surgically contaminated field. I disagree. If this were the case, one would not see the excellent safety data in the published literature regarding midurethral slings. The vagina can be prepped for surgery to minimize the chance of infection.

Plaintiffs' experts have also suggested that the TVT-Secur passes dangerously close to vital structures and the anatomic and positional variations in patients render inserter passage unreasonably hazardous. I disagree with this opinion. The TVT-Secur procedure involves the least and most superficial dissection of all sling procedures and traverses the fewest anatomic structures, none of which are major blood vessels or nerves. Continence surgeons are adept at identifying pelvic anatomy and commonly perform the simplest to the most complex pelvic surgery.

Plaintiffs' experts have also suggested that the removal of the TVT-Secur, if necessary, requires expertise that many implanting surgeons do not possess. First, it should be noted that removal of the entire TVT-Secur sling would be uncommonly indicated. If a patient has a small exposure, the exposed area can be removed in a short, simple procedure in many cases if conservative treatment such as topical estrogen cream does not resolve the issue. In the event of retention problems, the sling could be loosened postoperatively or

[26] Denis S, et al., Pelvic Organ Prolapse Treatment by the Vaginal Route Using a Vypro Composite Mesh: Preliminary Results About 106 Cases. ICS IUGA Abstract 620 (2004).

transected in a simple procedure. Although rarely necessary, the entire TVT-Secur mesh can be fully explanted as an uncomplicated, outpatient procedure.

d. Ethicon Product Literature—The Instructions for Use and Patient Brochures

The TVT-Secur device comes packaged with an Instructions for Use (IFU) document.[27] The IFU instructs the surgeon to "Please read all information carefully." It then notes that "[f]ailure to properly follow instructions may result in improper functioning of the Device and may lead to injury." It cautions that "[o]nly physicians trained in the surgical treatment of stress urinary incontinence should use the product." The IFU sets forth the indications and contraindications for use of the product and provides detailed instructions for how to use the device. The IFU also provides a list of warnings and precautions, noting, among other things:

- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT SECUR System before using.
- The GYNECARE TVT SECUR System should be performed with care to avoid large vessels, nerves, bladder and bowel. It is important to pay attention to the specific patient's anatomy while inserting the *Device*.
- Acceptable surgical practice should be followed for the GYNECARE TVT SECUR System as well as for the management of contaminated or infected wounds.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT SECUR System.

[27] ETH.MESH.00802340568–0755.

> To minimize this risk, make sure to place the tape as described above.

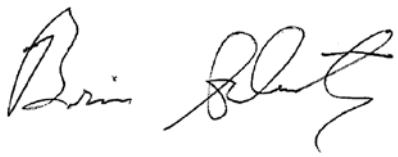
The IFU also includes a list of potential Adverse Reactions noting that punctures or lacerations of blood vessels, nerves, bladder, urethral, or bowel may occur, that transitory local irritation at the wound site and a transitory foreign body response may occur, which could result in extrusion, erosion, fistula formation, or inflammation, that infection may occur, and that over-correction or over tensioning may cause temporary or permanent lower urinary tract obstruction. In my opinion, these warnings and the detailed instructions for implanting the device are adequate. There is no need for Ethicon to warn surgeons about risks inherent in any pelvic floor surgery such as infection, inflammation, bleeding, scarring, bladder damage, bowel damage, nerve damage ureter damage, pain, pelvic pain, dyspareunia, groin pain, bladder or bowel dysfunction, fistula, anesthetic risks, wound complications such as erosion, wound dehiscence, exposure, wound herniation, hematoma, need for reoperation, failure of the operation, and anesthetic risks. Nor is there any need to warn surgeons about the severity, frequency, or permanency of any of these complications. Surgeons know from their education, training, and experience that complications can be mild, moderate, or severe, permanent or temporary, and data on complication frequency is available in peer-reviewed literature, which surgeons have an obligation to review. In my opinion, the warnings and instructions provided in the TVT-Secur IFU are adequate.

Ethicon also provided patient brochures to physicians to share those brochures with their patients if they saw fit. They are not a substitute for a thorough discussion between a patient and her physician regarding the treatment options and risks

and benefits of those options, but they are a helpful resource for patients. The brochures provide an overview of different types of urinary incontinence, treatment options, what MUS treatment involves, suggested questions for the patient to ask the physician, expected recovery from MUS surgery, and some of the risks of MUS surgery.

e. Professional Education

My initial exposure to the TVT-Secur was at an annual Gynecare preceptor's meeting. Using the TVT-Secur required minimal modification in implantation technique as this device was even less invasive than prior sling procedures. My first exposure to mesh slings included scientific and instructional lectures by academic leaders in the field of continence surgery. This was promptly followed by actively engaging in cadaver labs which included extensive discussion then dissection of pelvic anatomy. The MUS procedure was performed multiple times subsequent to which dissection of the cadaveric pelvis was performed. This unique opportunity afforded me the ability to assess and develop confidence and reproducibility of these procedures, as well as become more skilled at identifying and treating potential surgical complications. This combination of didactic and hands-on training contributed greatly to my knowledge of the scientific basis of continence, pelvic anatomy, and pelvic surgery skills.



Dated: 2/29/16 _____

Brian Schwartz, M.D.